IN THE US DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE CHATTANOOGA DIVISION

HEIKE DESSERT, individually and as Personal Representative of the Estate of RAYNALD DESSERT, deceased,	)	
Plaintiff,	)	
vs.	)	**Docket No._____**
BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC.,	)	**Jury Demand**
Defendants.	)	

COMPLAINT

COMES NOW Heike Dessert, individually, and in her representative capacity on behalf of surviving heirs as the Personal Representative of the Estate of Raynald Dessert, deceased, and brings this action for recovery of all lawful damages as a result of the tragic, untimely and unnecessary death of her husband, Raynald Dessert, and for her Complaint against the defendants, states as follows:

NATURE OF THE CASE

1. This action is brought by Heike Dessert, individually, and as Personal Representative of the Estate of Raynald Dessert, deceased, for the recovery of all fair, just and reasonable damages allowed by law for personal injuries to and for the wrongful death of Raynald Dessert along with all derivative damages, consistent with the facts, law and causes of action set forth below.

2. Heike Dessert's deceased husband, Raynald Dessert, was prescribed Eliquis, also known as apixaban, to reduce the risk of stroke and embolism.

3. Defendants Bristol-Myers Squibb Company and Pfizer, Inc. (hereinafter collectively referred to as "defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Eliquis, as well as dealt with governmental regulatory bodies.

4. In written information about the safety and risks of Eliquis, defendants negligently and fraudulently represented to the medical and healthcare community, including Raynald Dessert's prescribing doctor, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Raynald Dessert, and the public in general that Eliquis had been tested and was found to be safe and effective for its indicated uses.

5. Defendants concealed their knowledge of Eliquis' defects from Raynald Dessert, the FDA, the public in general, and the medical community, including Raynald Dessert's prescribing doctor.

6. These representations were made by defendants with the intent of defrauding and deceiving Raynald Dessert, the public in general, and the medical and healthcare community, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and purchase Eliquis, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the general public at large.

7. As a result of the foregoing acts and omissions, Raynald Dessert was caused to suffer serious and dangerous side effects including bleeding, physical pain, mental anguish and death.

PARTIES

8. Prior to his tragic, untimely and unnecessary death, Raynald Dessert was and Heike Dessert, individually, and as Personal Representative of the Estate of Raynald Dessert,

deceased, is a citizen and resident of 186 County Road 853, Delano, Polk County, Tennessee 37325.

9. Upon information and belief, defendant, Bristol-Myers Squibb Company (hereinafter "BMS") was and is a for-profit company incorporated and/or organized under the laws of Delaware, with a principal place of business at 345 Park Ave., New York, NY 10154-0004. BMS is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 800 S. Gay Street, Suite 2021, Knoxville, TN 37929-9710. Defendant BMS is the holder of the approved New Drug Application ("NDA") for Eliquis as well as the supplemental NDA. As part of its business, BMS was and is involved in the research, development, sales, and marketing of pharmaceutical products including Eliquis. At all relevant times, Defendant BMS was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Eliquis for use as an oral anticoagulant in this judicial district, throughout the United States, and the world.

10. Upon information and belief, defendant Pfizer, Inc. (hereinafter "Pfizer") was and is a for-profit corporation incorporated and/or organized under the laws of Delaware, with a principal place of business at 235 E. 42nd Street, New York, NY 10017-5703. Pfizer is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 800 S. Gay Street, Suite 2021, Knoxville, TN 37929-9710. Defendant Pfizer was and is in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Eliquis for use as an oral anticoagulant in this judicial district, throughout the United States, and the world. In 2007, Defendants entered into a worldwide collaboration to "commercialize" apixaban (Eliquis), which they have promoted as

combining BMS's "long-standing strengths in cardiovascular drug development and commercialization" with Pfizer's "global scale and expertise in this field."

JURISDICTION AND VENUE

11. This Honorable Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A) in that there exists complete diversity of citizenship between the parties and the amount in controversy, exclusive of interest and costs, exceeds Seventy-Five Thousand Dollars ($75,000.00).

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a). A substantial portion of the events and omissions giving rise to this action occurred in this District.

13. This Court has personal jurisdiction over each of the parties as the defendants actively designed, manufactured, marketed, sold, and/or distributed their pharmaceutical product, Eliquis (apixaban) in Tennessee. The defendants placed the subject pharmaceutical product into the channels of commerce with knowledge that a substantial number of such products would be used in Tennessee. The defendants regularly conduct and solicit business in the state of Tennessee and derive substantial revenue from goods used and consumed in Tennessee.

FACTUAL BACKGROUND

14. At all relevant times, defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Eliquis as an oral anticoagulant, also known as a Factor Xa inhibitor.

15. Defendants received FDA approval to market Eliquis in 2012 (NDA 202155). Among the uses for which it obtained permission to market Eliquis was in the treatment of atrial fibrillation and other cardiovascular diseases and to prevent stroke and embolism.

16. Approval of Eliquis was based in large part on clinical trials known as ARISTOTLE. The ARISTOTLE study was conducted under the supervision and control of defendants, in various countries, including China. Defendants, as means of cutting costs, chose incompetent and untrustworthy agents in China to conduct the ARISTOTLE study.

17. Defendants' agents committed fraud in their conduct of the ARISTOTLE study, by concealing side effects which occurred in test users of Eliquis; a death which went unreported (whereas one purpose of the study was to study the rate of death in Eliquis users compared to others in Coumadin); loss of subjects to follow up; major dispensing errors including indicating that certain subjects were getting Eliquis when they were not; poor overall quality control; and changing and falsifying records, including records disappearing just before the FDA made a site visit, reportedly on the order of an employee of BMS.

18. At a Feb. 9, 2012, meeting between the FDA and BMS-Pfizer executives, the FDA is reported to have characterized the conduct of defendants as showing a pattern of inadequate supervision.

19. Defendants market Eliquis as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. Defendants emphasize the supposed benefits of treatment with Eliquis over warfarin, in that Eliquis does not require periodic monitoring with blood tests and did not limit a patient's diet, and that a set dose fits all patients.

20. When the application by defendants to the FDA was pending, in 2012, Dr. Thomas Marcinak, a physician in the FDA who reviewed the data submitted by defendants in order to obtain approval to market Eliquis, objected to missing data from the ARISTOTLE study

and recommended that the labeling which defendants were going to use with the drug should discuss the quality control problems in ARISTOTLE, the Chinese study.

21. Instead of admitting the major errors and frauds involved in the ARISTOTLE study, defendants misleadingly stated publically that they were submitting "additional data" to the FDA, and to this date have never publically acknowledged the missing and incorrect data submitted to the FDA, which would be of concern to prescribing physicians and the public.

22. After employees of defendants wrote and submitted an article based on the ARISTOTLE study for the New England Journal of Medicine, the article was reportedly attacked for its accuracy and omissions by the former editor-in-chief of that journal, Arnold Relman, M.D., including the failure to show that Eliquis was any more efficacious than low-cost warfarin.

23. Critically, there is no antidote to Eliquis, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available or validated reversal agent or antidote, as there is for Coumadin.

24. The U.S. label approved when the drug was first marketed in the U.S., and at the time Raynald Dessert was using it, did not contain an adequate warning regarding the lack of antidote, and the significance of that problem for patients who began to bleed.

25. After the drug was approved by the FDA, defendants engaged in an aggressive marketing campaign for Eliquis, including extensive marketing directly to the public via TV and print. The chief promotional aspect of the sales pitch was that, unlike with Coumadin, the blood levels of the patient did not need to be monitored.

26. In the course of these direct-to-consumer advertisements, defendants overstated the efficacy of Eliquis with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the

anticoagulation effects of Eliquis, and that such irreversibility would have life-threatening and fatal consequences.

27. Prior to Raynald Dessert's use of Eliquis, he became aware of the promotional materials described herein.

28. Prior to Raynald Dessert's use of Eliquis, upon information and belief, Raynald Dessert's prescribing physician received promotional materials and information from sales representatives of Defendants that Eliquis was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation and treating other cardiovascular conditions, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Eliquis.

29. At all times relevant hereto, defendants also failed adequately to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Eliquis, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Eliquis.

30. Before and after marketing Eliquis, defendants became aware of many reports of serious hemorrhaging in users of its drugs, both as reported to the FDA and to it directly. Yet defendants have never disclosed to the medical profession or patients what the incidences of such adverse reactions are.

31. Despite the clear signal generated by the side effect data, defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Eliquis.

32. Defendants' product labeling and prescribing information for Eliquis was inadequate in that it:

(a) failed to investigate, research, study and define, fully and adequately, the safety profile of Eliquis;

(b) failed to provide adequate warnings about the true safety risks associated with the use of Eliquis;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Eliquis and its effects on the degree of anticoagulation in a patient;

(d) failed to provide adequate warning that it is difficult or impossible to assess the degree and extent of anticoagulation in patients taking Eliquis;

(e) failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis;

(f) failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Eliquis;

(g) failed to provide adequate instructions on how to intervene and stabilize a patient who suffers a bleed while taking Eliquis;

(h) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Eliquis users;

(i) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Eliquis, especially, in those patients with a prior history of gastrointestinal issues and upset;

(j) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Eliquis;

(k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Eliquis and to continue testing and monitoring of renal functioning periodically while the patient is on Eliquis;

(l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Eliquis and to continue testing

and monitoring of hepatic functioning periodically while the patient is on Eliquis;

(m) failed to include a "BOXED WARNING" about serious bleeding events associated with Eliquis;

(n) failed to include a "BOLDED WARNING" about serious bleeding events associated with Eliquis; and

(o) in their "Medication Guide" intended for distribution to patients to whom Eliquis has been prescribed, defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Eliquis and that if serious bleeding occurs, such irreversibility could have permanently disabling, life- threatening or fatal consequences.

33. As a result of defendants' aggressive marketing efforts, it had sales of $774 million in 2014, of which $281 million was just for the fourth quarter alone. Eliquis has been referred to by the defendants as a blockbuster drug. In support of its aggressive marketing, defendants jointly paid more than $8 million to doctors in 2013, according to ProPublica/NY Times.

34. Despite life-threatening bleeding findings in clinical trials and in other clinical evidence, defendants failed to adequately conduct complete and proper testing of Eliquis prior to filing their New Drug Application for Eliquis.

35. From the date defendants received FDA approval to market Eliquis, defendants made, distributed, marketed, and sold Eliquis without adequate warning to Raynald Dessert or his prescribing physicians that Eliquis was associated with and could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that defendants had not adequately conducted complete and proper testing and studies of Eliquis with regard to severe side effects, specifically life-threatening bleeding.

36. Upon information and belief, defendants concealed and failed to completely disclose its knowledge that Eliquis was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

37. Defendants ignored the association between the use of Eliquis and the risk of developing life-threatening bleeding.

38. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Eliquis for life-threatening bleeding risk further rendered warnings for this medication inadequate.

39. In addition, the Eliquis package insert minimized and failed to fully and accurately communicate the risk of severe cutaneous reactions.

40. By reason of the foregoing acts and omissions, Raynald Dessert endured and suffered physical pain and mental anguish, diminished enjoyment of life, and ultimately death. His family has become liable for certain medical treatment costs and funeral and burial expenses as result of the acts and omissions of the defendants as stated in this Complaint.

SPECIFIC FACTUAL BACKGROUND

41. Prior to his death, Raynald Dessert had a known medical history of coronary artery disease, chronic obstructive pulmonary disease with significant hypoxic respiratory failure, peripheral vascular disease, hyperlipidemia, peripheral artery disease, hypertension, and chronic bronchitis.

42. On or about July 17, 2015, Raynald Dessert attended a doctor appointment with his oncologist, Albert M. Petty, M.D. at his office located at Blount Memorial Hospital, 907 East Lamar Alexander Parkway, Maryville, Tennessee 37804. Raynald Dessert was a patient of Dr.

Petty because in April of 2015, he was diagnosed with small cell lung cancer that ultimately spread to his liver.

43. During this visit, Dr. Petty prescribed Eliquis to treat Raynald Dessert's cardiovascular diseases and other health conditions. Raynald Dessert began taking the medication as prescribed on or about July 17, 2015. Raynald Dessert took the Eliquis for approximately three months before discontinuing the medication due to excessive bleeding.

44. Not long after taking the medication, Raynald Dessert began experiencing episodes of bleeding. He initially presented to Blount Memorial Hospital on September 9, 2015 due to anal bleeding. He was sent for further testing to determine the source of the bleeding but none was located. He presented to Blount Memorial Hospital again on September 30, 2015. Testing indicated he had lost 6 pints of blood. He was admitted to the hospital for transfusions and required weekly or bi-weekly transfusions during the time he took the Eliquis. The doctors discontinued the Eliquis after three months but the damage was irreversible.

45. On February 1, 2016, Raynald Dessert died as a result of complications from taking the Eliquis.

46. Raynald Dessert was not sufficiently warned that Eliquis is an unreasonably dangerous product, even when used exactly as the manufacturer intended. Defendants promoted, marketed and sold Eliquis to Raynald Dessert and other consumers, and healthcare providers, and held out to the FDA that Eliquis was safe for its intended purposes. Raynald Dessert died as a result of receiving this unreasonably dangerous oral anticoagulant, which was unfit for the purpose it was designed, manufactured, marketed and sold.

47. Raynald Dessert's death as a result of taking Eliquis was caused by, and was the direct and proximate result of the defective and dangerous products manufactured, designed and

distributed by the defendants as well as their breaches of warranty and negligence, and other wrongful conduct by and through their agents, servants, and employees.

CLAIMS FOR RELIEF

COUNT I
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

48. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

49. At all relevant times, defendants designed, engineered, developed, manufactured, researched, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed into the stream of commerce, in the regular course of their business, Eliquis oral anticoagulant medication that is the subject of this lawsuit. Defendants sold Eliquis and other oral anticoagulant products to consumers such as Raynald Dessert. At all relevant times, defendants had a duty to design the medication at issue in this case in a reasonable manner.

50. The defendants knew or should have known that Eliquis was defective when it was designed and manufactured and at the time it left their control.

51. The defendants are strictly liable to Raynald Dessert because the Eliquis he took was defective and unreasonably dangerous for normal use as a direct and proximate result of defective design and manufacture of the medication that was known or should have been known at the time of the designing, engineering, development, manufacturing, assembly, inspection, testing, packaging, labeling, promotion, marketing, buying, selling and/or distribution of the drug.

52. The defendants designed, engineered, developed, manufactured, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed into the stream of commerce, in the regular course of their business, defective and unreasonably

dangerous products such as Eliquis and other oral anticoagulants knowing that the said products would reach and did reach the consumer without substantial change in defective conditions from the date the products left the defendants' control.

53. When Eliquis was manufactured and sold by the defendants, the product was defective in design and formulation, making use of it more dangerous than with similar anticoagulation medications.

54. The defendants knew or should have known that the ultimate consumer of their products would not, and could not, properly inspect Eliquis so as to discover the latent defects described herein. The product reached consumers and the general public without substantial change. The product was defective when it left control of these defendants.

55. The defendants knowingly and deliberately designed, manufactured and sold Eliquis and other oral anticoagulation products with design defects and then failed to adequately correct the defects or warn the public of the possible dangers.

56. The conduct of the defendants was willful and wanton and showed a conscious disregard for the safety of the public and consumers. The defendants' actions and omissions in knowingly designing, manufacturing, and selling, and then failing to adequately correct known defects were intentional, willful, wanton and showed a total disregard for the safety of the general public.

57. The design defects of Eliquis caused severe physical, mental, and emotional injuries and death to Raynald Dessert. Raynald Dessert's injuries and death and the injuries and damages suffered by his wife and family were the direct and proximate result of the design defects of Eliquis he was prescribed that is the subject of this lawsuit.

COUNT II
STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING

58. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

59. At all relevant times, defendants designed, engineered, developed, manufactured, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed into the stream of commerce, in the regular course of their business, Eliquis oral anticoagulant medication that is the subject of this lawsuit. Defendants sold Eliquis and other oral anticoagulant products to consumers such as Raynald Dessert. At all relevant times, defendants had a duty to manufacture the subject pharmaceutical products at issue in this case in a reasonable manner.

60. The defendants knew or should have known that Eliquis was defective when it was designed and manufactured and at the time it left their control.

61. The defendants are strictly liable to Raynald Dessert because the Eliquis he took was defective and unreasonably dangerous for normal use as a direct and proximate result of defective design and manufacture of the medication that was known or should have been known at the time of the designing, engineering, development, manufacturing, assembly, inspection, testing, packaging, labeling, promotion, marketing, buying, selling and/or distribution of the drug.

62. The defendants designed, engineered, developed, manufactured, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed into the stream of commerce, in the regular course of their business, defective and unreasonably dangerous products such as Eliquis and other oral anticoagulants knowing that the said products would reach and did reach the consumer without substantial change in defective conditions from the date the products left the defendants' control.

63. When Eliquis was manufactured and sold by the defendants, the product was defective in design and formulation, making use of it more dangerous than with similar anticoagulation medications.

64. The defendants knew or should have known that the ultimate consumer of their products would not, and could not, properly inspect oral anticoagulation medications such as Eliquis so as to discover the latent defects described above. The product reached consumers and the general public without substantial change. The product was defective when it left control of these defendants.

65. The defendants knowingly and deliberately designed, manufactured and sold Eliquis with manufacturing defects and then failed to adequately correct the defects or warn of the possible dangers.

66. The conduct of the defendants was willful and wanton and showed a conscious disregard for the safety of the public and consumers. The defendants' actions and omissions in knowingly designing, manufacturing, and selling, and then failing to adequately correct known defects were intentional, willful, wanton and showed a total disregard for the safety of the general public.

67. The manufacturing defects of Eliquis caused severe physical, mental, and emotional injuries and death to Raynald Dessert. Raynald Dessert's injuries and death and the injuries and damages suffered by his wife and family were the direct and proximate result of the design defects of the Eliquis he was prescribed that is the subject of this lawsuit.

COUNT III
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

68. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

69. At all relevant times, the defendants designed, engineered, developed, manufactured, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed into the stream of commerce, in the regular course of their business, anticoagulation medication including Eliquis that they knew would be purchased by consumers such as Raynald Dessert. At all relevant times, the defendants had a duty to adequately warn consumers such as Raynald Dessert and the general public of any defects.

70. The defendants are strictly liable to Raynald Dessert because the Eliquis he took was defective and unreasonably dangerous for normal use due to its defective design, manufacture and distribution and due to defendants' failure to provide adequate warnings of the substantial dangers known or knowable at the time of the designing, engineering, development, manufacturing, assembly, inspection, testing, packaging, labeling, promotion, marketing, buying, selling and/or distribution of the drug.

71. The defendants designed, engineered, developed, manufactured, assembled, inspected, tested, packaged, labeled, promoted, marketed, bought, sold and/or distributed, and placed on the market and into the stream of commerce defective drugs such as Eliquis that were unreasonably dangerous to the patient, knowing that the products would reach and did reach the ultimate consumer and the general public in this case without substantial change in the defective conditions they were in from the date when they left each defendants' control.

72. The defendants knew or should have known that the ultimate users or consumers of the subject products and the general public would not, and could not, properly inspect Eliquis so as to discover the latent defects described above. The drug reached hospitals, physicians, patients and the public without substantial change. The product was defective when it left control of the defendants.

73. At the time of Raynald Dessert's injuries and damages, Eliquis was being used in a manner that was reasonably foreseeable by defendants as involving a substantial danger not readily apparent to the public. Adequate warnings of the dangers were not given.

74. Defendants' conduct was willful and wanton and showed a conscious disregard for the safety of the general public and consumers such as Raynald Dessert. Defendants actions and omissions in knowingly designing, manufacturing, and selling, and then failing to adequately correct known defects or warn potential patient recipients of their medications were intentional, willful, wanton and showed a total disregard for the safety of individuals such as Raynald Dessert.

75. Raynald Dessert's injuries, damages and death were the direct and proximate result of the defendants' failure to adequately warning him and the general public about the potential dangers of Eliquis that is the subject of this lawsuit.

COUNT IV
BREACH OF EXPRESS WARRANTY

76. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

77. Defendants' promotional statements and/or product instructions concerning Eliquis contained broad, express claims amounting to a warranty that it was safe and effective, and not defective, for the purposes for which it was marketed and sold.

78. Defendants breached their warranty by offering for sale, and selling as safe and non-defective, Eliquis, which in fact was unsafe and defective in respect to the designing, engineering, development, manufacturing, assembly, inspection, testing, packaging, labeling, promotion, marketing, buying, selling and/or distribution.

COUNT V

BREACH OF IMPLIED WARRANTY

79. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

80. Defendants impliedly warranted that Eliquis (which defendants designed, developed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, distributed and eventually sold to the public, including Raynald Dessert), was fit and safe for ordinary use. Defendants further impliedly warranted that Eliquis was fit for its particular purpose.

81. Eliquis was and is defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which it was sold, and subjected the public and Raynald Dessert to severe physical and mental injuries and/or death. Therefore, defendants breached the implied warranties of merchantability and fitness for a particular purpose when the drug was sold to the public and to Raynald Dessert, in that the medication was defective and failed to function as represented and intended.

COUNT VI
CONSTRUCTIVE FRAUD

82. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

83. At the time of selling Eliquis to medical providers and to the public, the defendants were in a unique position of knowledge concerning the safety and effectiveness of the products, which knowledge was not possessed by medical professionals and the public, and defendants thereby held a position of superiority over medical professionals, the public and Raynald Dessert.

84. Through their unique knowledge and expertise regarding the defective nature of Eliquis, and through the statements made in advertisements, promotional materials, and other

communications, defendants professed to the public that they had knowledge of the truth of the representation that Eliquis was safe for its intended use and was not defective.

85. Defendants' representations to the public were unqualified statements made to induce physicians to prescribe and the public to use Eliquis, and physicians and the public relied upon the statements when prescribing the medicine and using it as directed.

86. The defendants took unconscionable advantage of their dominant position of knowledge with regard to the public and engaged in constructive fraud in their relationship with medical providers and the public, including Raynald Dessert, all of whom reasonably relied on defendants' representations.

COUNT VII
NEGLIGENCE

87. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

88. Defendants had a duty to the public and Raynald Dessert to provide a safe product in design and manufacture and to notify and to warn the public and Raynald Dessert of the defective and dangerous nature of Eliquis. Defendants breached their duty of reasonable care to the public and to Raynald Dessert by incorporating a defect into the design and manufacture of the medication and by failing to provide adequate warning, thereby causing injuries and death.

89. Defendants breached their duty of reasonable care to the public by designing and manufacturing Eliquis in such a manner that it was prone to expose the public and Raynald Dessert to unnecessary injury and trauma.

90. Defendants breached their duty of reasonable care to the public and Raynald Dessert by failing to notify the public at the earliest possible date of known design and/or manufacturing defects in and/or side effects of Eliquis.

91. Defendants breached their duty of reasonable care to the public and Raynald Dessert by failing to use due care under the circumstances and in the testing, inspection, manufacture, and design of Eliquis to avoid the risks of injury to someone like Raynald Dessert.

92. Defendants breached their duty of reasonable care to the public and Raynald Dessert by failing to manufacture the products in accordance with proper manufacturing specifications and by failing to manufacture the products identically in all material aspects as other safe anticoagulation medications.

93. Defendant breached their duty of reasonable care to the public and Raynald Dessert by failing to adopt existing feasible design alternatives that would have prevented the harm to Raynald Dessert without impairing the utility, usefulness, practicality and desirability of the medication.

94. Defendants breached their duty of reasonable care to the public and Raynald Dessert by failing to hire competent and qualified personnel to design, manufacture and sell their drug.

COUNT VIII
NEGLIGENCE PER SE

95. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

96. As defined by the laws and statutes of the State of Tennessee, including, but not limited to the Tennessee Products Liability Act of 1978, T.C.A. § 29-28-101, *et seq.*, the defendants allowed tangible goods, Eliquis, to be placed into the stream of commerce and distributed to the general public and to expose the public to the said products.

97. Eliquis was unreasonably dangerous at the time it left the defendants' possession as it was dangerous to an extent beyond that which would be contemplated by the general public

who is prescribed the medication. Eliquis was also placed in the stream of commerce in defective condition, as it was unsafe for normal or anticipatable handling and consumption.

98. As a consequence of the defendants' acts and omissions in violation of the above statutes, Raynald Dessert suffered serious bodily injuries and death that would not have otherwise occurred.

COUNT IX
VIOLATION OF CONSUMER PROTECTION STATUTES

99. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

100. Under statutes enacted in Tennessee, including without limitation the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq*., codified to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Raynald Dessert is a consumer who was prescribed, purchased, and took Eliquis at the direction of a physician and is therefore subject to protection under such legislation.

101. Under the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq*., codified to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the defendants are suppliers, manufacturers, advertisers, and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

102. Defendants violated the statutes enacted in Tennessee, including without limitation the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq*., by failing to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Eliquis was

fit to be used for the purpose for which it was intended, when in fact the product was defective and dangerous, and by other acts alleged herein.

103. The actions of the defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Tennessee, including without limitation the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq*., due to the defendants' failure in protecting consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

104. The defendants manufactured, marketed and designed the drug Eliquis which was defective or unreasonably dangerous for its intended and recommended use within the meaning of Tenn. Code Ann. § 29-28-102(2) and (a).

105. Because Eliquis was defective, the defendants breached express warranties as defined by Tenn. Code Ann. § 47-2-313.

106. Because Eliquis was defective, the defendants breached implied warranties of merchantability as set forth in Tenn. Code Ann. § 47-2-314.

107. Because Eliquis was defective, the defendants breached implied warranties of fitness for particular purposes as set forth in Tenn. Code Ann. § 47-2-315.

108. Defendants had actual knowledge of the defective and dangerous condition of Eliquis, and failed to take any action to cure such defective and dangerous condition, well in excess of any reasonable time before the public and Raynald Dessert did or could have possessed any such knowledge.

COUNT X
PUNITIVE DAMAGES

109. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

110. At all material times, the defendants knew or should have known that Eliquis was inherently more dangerous than other similar prescription anticoagulation drugs developed, manufactured, tested, packaged, labeled, marketed, sold and/or distributed into the stream of commerce.

111. At all material times, the defendants attempted to misrepresent and did misrepresent facts and withheld material information concerning Eliquis.

112. At all material times, the defendants knew and recklessly disregarded the fact that Eliquis was and is unreasonably dangerous and defective.

113. Despite their knowledge, the defendants continued to aggressively market Eliquis to consumers, including Raynald Dessert, without disclosing or warning of the latent design and manufacturing defects.

114. The defendants knew of the defective and unreasonably dangerous nature of Eliquis but continued to design, develop, manufacture, market, distribute and sell the drug so as to maximize sales and profits at the expense of the health and safety of the public in conscious and/or negligent disregard of the foreseeable harm that such products could cause.

115. Defendants intentionally concealed and/or recklessly failed to disclose the potentially dangerous manufacturing and design defects inherent in Eliquis in order to ensure continued and increased sales and profits.

116. A verdict for punitive damages should be granted against the defendants because the defendants' failure to warn was reckless and without regard for the public's safety and welfare. The defendants misled the public at large, by making false representations and failing to disclose the dangers inherent with taking Eliquis. Defendants' actions and/or inactions were willful and wanton.

117. As a direct and proximate result of the defendants' conscious and deliberate disregard for the rights and safety of the public and consumers, Raynald Dessert suffered severe physical injuries, substantial pain and suffering, and death. As a result, Raynald Dessert seeks actual and punitive damages from the defendants.

118. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of the public and consumers thereby making it appropriate to grant a verdict for punitive damages in an amount appropriate to punish the defendants and deter them from similar conduct in the future.

DAMAGES

119. The allegations of the prior paragraphs are repeated and re-alleged as if set forth at length herein.

120. As a direct and proximate result of the negligent acts and negligent omissions of the defendants as stated above, Raynald Dessert suffered grievous injuries, and horrible physical and mental pain and suffering, and death, which would not have occurred absent the defendants' negligence, actions and omissions.

121. As a direct and proximate result of the negligent acts and negligent omissions of the defendants, Raynald Dessert and surviving spouse Heike Dessert incurred reasonable and necessary medical and other expenses reasonably required to treat Raynald Dessert's injuries resulting from taking Eliquis. Additionally, Heike Dessert incurred reasonable and necessary funeral and burial costs because of the death of her husband.

122. As a direct and proximate result of the negligence of the defendants, Heike Dessert has been deprived of the love, services, society, advice, companionship, and/or

consortium of her husband Raynald Dessert and will continue to be deprived of the same to her great detriment and loss in the future.

PRAYER FOR RELIEF

WHEREFORE, based upon the aforesaid individual counts and the Complaint as a whole, Heike Dessert, individually, and as Personal Representative of the Estate of Raynald Dessert, deceased, prays as follows:

(1) For a fair, reasonable and appropriate verdict against defendants for compensatory damages in an amount not to exceed twelve million five hundred thousand ($12,500,000.00) dollars;

(2) For a fair, reasonable and appropriate verdict against all defendants for punitive damages in an amount not to exceed fifty million ($50,000,000.00) dollars;

(3) For a fair, reasonable and appropriate verdict against defendants for all discretionary costs allowed by law;

(4) For a fair, reasonable and appropriate verdict against defendants for all post-judgment interest allowed by law;

(5) For all such other and further relief as this Court deems just and proper; and

(6) For a jury of twelve to try the issues when joined.

Heike Dessert, individually, and in her representative capacity on behalf of herself and surviving heirs as the Personal Representative of the Estate of Raynald Dessert, deceased
Plaintiff by attorneys

Respectfully submitted,

BILBO LAW OFFICE, P.C.

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